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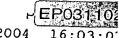
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JC13 Rec'd PCT/PTO 91 APR 2009

New Set of Claims

- 1. A process for the expansions of TALL lymphocytes, wherein at least 1x10° cells are grown in homogeneous conditions in a single fermentation unit.
- The process as claimed in claim 1, wherein said fermentation unit is for anchorage dependent cells.
 - 3. The process as claimed in claim 1, wherein said fermentation unit is a multichamber stack.
 - 4. The process as claimed in claim 3, wherein said fermentation unit is a Cell-Factory™.
 - 5. The process as claimed in claim 3, wherein the expansion in the homogeneous system is preceded by a process of pre expansion in flask until obtaining a number of cells from 0.7 to $1x10^8$.
- 6. The process as claimed in claim 5, wherein the cellular density of the inoculum is at least 0.7x10⁸ cells/ml and is preferably equal to 0.75x10⁸ cells/ml and, at the harvest time, the density is lower than 2x10⁶ cells/ml, preferably than 1x10⁶.
 - 7. The process as claimed in claim 4, wherein the Cell-Factory™ is a 10-chamber unit.
- 8. The process as claimed in claim 1, wherein TALL lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
 - 9. Process according to claim 8 wherein TALL are TALL-104 lymphocytes.
 - 10. The process as claimed in any of claims 1 to 9, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% max human serum, preferably in the range of 4 to 6%, still more preferably of 5%, optionally foetal serum in a concentration of 0 to 10% and interleukin in a concentration of 100!U/ml.
 - 11. The process as claimed in claim 10, wherein interleukin-2 is added to the cell culture every 48-90 hrs.
- 12. The process as claimed in claim 10, wherein the cell growth in the homogeneous system takes place in an antibiotic-free culture medium.



- 13. A process for the preparation of frozen bags of TALL lymphocytes in an amount of at least $1x10^9$ cells, characterized in the fact it comprises the process according to claims 1 12.
- 14. Process as claimed in claim 13, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.
- 15.Process for the preparation of a therapeutic dose of at least 1x10⁹ TALL lymphocytes in a homogeneous culture characterized in the fact it comprises the process according to claims 1 12.
- 16. The process as claimed in claim 15, wherein the lymphocytes are TALL-104.
- 17. TALL lymphocytes obtainable according to the process of claims 1 12 wherein said lymphocytes are characterised by a CD3⁺ and CD8⁺ immunologic markers expression of 98% min, preferably ≥99%, and by the CD56⁺ marker expression of 95% at least, preferably ≥97%.
- 18. TALL lymphocytes according to claim 17 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.

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